

REMARKS

Status of the claims:

With the above amendments, claim 1 has been amended. Claims 1 and 2 are pending and ready for further action on the merits. No new matter has been added by way of the above amendments. Support for the amendment to claim 1 can be found at page 2, line 17 and at page 7, lines 7-9. Entry of the amendment and reconsideration is respectfully requested in light of the following remarks.

Rejections under 35 USC §112, first paragraph

Claims 1-2 are rejected under 35 USC §112, first paragraph as allegedly containing new matter. The Examiner asserts that there is no support in the specification for "staining red blood cells isolated as the sample". Applicant has amended claim 1 to recite "staining red blood cells in a peripheral blood sample in hypotonic solution with PE conjugated antihemoglobin (anti-Hb) antibody", which has support at page 2, lines 17-19, page 1, line 13, and the caption for Table 1, that says "the proportion of red blood cells stained with anti-Hb antibody in 0.6% NaCl in each disease group". Thus, Applicant believes that the claims as they now stand are fully supported by the written description so that one of skill in the art would recognize that Applicant

was in full possession of the currently claimed invention at the time of filing the application. Withdrawal of the rejection is warranted and respectfully requested.

The Examiner has indicated that the rejection over BD Biosciences might be reinstated with the above claim amendment. However, Applicant submits that this reinstatement would be inapposite as BD Biosciences does not disclose a diagnostic method for hemolytic anemia as is currently claimed in the instant invention. Thus, Applicant asserts that the Examiner has failed to make out a *prima facie* case of obviousness with regard to the 35 USC §103(a) rejection over the BD Biosciences reference. Three criteria must be met to make out a *prima facie* case of obviousness.

- 1) There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.
- 2) There must be a reasonable expectation of success.
- 3) The prior art reference (or references when combined) must teach or suggest all the claim limitations.

See MPEP §2142 and *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991). In particular, the Examiner has failed to meet any of the elements necessary to make a proper *prima facie* rejection.

First, there is no suggestion or motivation provided in BD Biosciences to modify the reference to arrive at the instant invention. This is because BD Biosciences fails to disclose or remotely suggest diagnosing hemolytic anemia. Accordingly, for this reason alone, the BD Biosciences reference cannot render the instant invention *prima facie* obvious.

Second, Applicant also submits that there is also no expectation of success. Because BD Biosciences does not disclose or remotely suggest using fragmented red blood cells in their assay or disclose or remotely suggest a diagnostic method of hemolytic anemia, one would never have any expectation of success. Thus, for this reason also, Applicant submits that BD Biosciences cannot render *prima facie* obvious the instant invention.

Third, all of the elements of the instant invention have not been disclosed. As mentioned above, BD Biosciences fails to disclose or remotely suggest performing a diagnostic assay for hemolytic anemia. Thus, BD Biosciences cannot render the instant invention *prima facie* obvious.

Even if BD Biosciences were to render the instant invention *prima facie* obvious, which the Applicant does not concede, Applicant submits that the instant invention shows unexpectedly superior results over BD Biosciences. The instant invention can be performed with sample sizes as small as 2 μ l. One of skill in

the art would never contemplate that this could be achieved in reading the BD Biosciences reference, which discloses using sample sizes of 20 μ l. Thus, Applicant believes that the rejection is inapposite for this reason also. Withdrawal of the rejection is warranted and respectfully requested.

Rejections under 35 USC §112, second paragraph

Claims 1 and 2 are rejected under 35 USC §112, second paragraph as being indefinite. The Examiner asserts that there is no correlation between the method steps as set out in current claim 1 and the method of determining whether a sample is from a patient that has hemolytic anemia. Applicant has amended claim 1 to address this issue. In particular, claim 1 has been amended to recite "wherein said diagnostic method of hemolytic anemia shows stained red blood cells of more than 1%". There is support for this amendment at page 6, lines 5-7. Accordingly, Applicant now believes that the rejection has been obviated as there is a correlation between the method of the instant invention and detecting whether an individual has hemolytic anemia. Withdrawal of the rejection is warranted and respectfully requested.

With the above remarks and amendments, Applicant believes that the claims, as they now stand, define patentable subject

matter such that passage of the instant invention to allowance is warranted. A Notice to that effect is earnestly solicited.

If any questions remain regarding the above matters, please contact Applicant's representative, T. Benjamin Schroeder (Reg. No. 50,990), in the Washington metropolitan area at the phone number listed below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By



James T. Eller, Jr. #39,538

BS
JTE/TBS/mua

P.O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000